UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,760	09/27/2005	Anders Ljunggren	133087.09001	3784

52286 7590 09/30/2008

Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183

EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,760	LJUNGGREN ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 14-20* is/are pending in the application.

4a) Of the above claim(s) *14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/25/2008 has been entered.

Election/Restrictions

2. The species under examination is expanded to include Compound I:4, which is necessitated by the claim amendment cancelling Compound I:2.

Response to Arguments

3. Applicants' arguments, filed 6/25/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

4. Applicant's arguments, see pp. 5-6, filed 6/25/2008, with respect to the rejection(s) of claim(s) 11 and 17-20 under 35 USC 102 & 103 and 35 USC 112, 2nd paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows.

The rejections under 35 USC 102 & 103 are withdrawn due to the claim amendment eliminating the compound of formula I, where A is I:2 from the claims. The rejections that follow are necessitated by the claim amendment eliminating the specie on which the previous rejections were based.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 11 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortlepp et al. ("Inhibition of the rennin-angiotensin system ameliorates genetically determined hyperinsulinemia"; 2002; European Journal of Pharmacology; 436: 145-150: IDS 3/25/2008 reference 1) and Yoneyama, et al. ("Cardiovascular Effects of L-158,809, a New Angiotensin Type 1 Receptor Antagonist, Assessed Using the Halothane-Anesthetized In Vivo Canine Model"; 2002; Jpn. J. Pharmacol.; 89: 193-196) in view of STN (RN 133240-46-7; 1991; accessed 9/15/2008).

This rejection is necessitated by the amendment to the claims, cancelling Compound I:2, on which the previous rejection was based. Ortlepp teaches the effects of angiotensin II receptor antagonist, irbesartan on the metabolic syndrome in an animal model, concluding long term treatment with an angiotensin-converting enzyme inhibitor or an angiotensin II receptor antagonist can ameliorate obesity and hyperinsulinemia in a genetically determined mouse model (abstract); initial administration of 0.0625 mg/g weight/day irbesartan, increasing to 0.2125mg/g at the age of 16 weeks was required to maintain an equipotent effect in reduction of blood pressure compared with captopril treatment (p. 146; Medication section); mice treated with Irbesartan had a body weight of 38.3 and a body weight gain and a gain of body weight of 4.3 g (Table 2); 0.0625mg/g x (38.3-4.3 g) corresponds to 2.0125 mg initial dosage; 0.2125mg/g x 38.3 g corresponds to 8.13875 g dosage at age 16 weeks. Ortlepp does not teach administration of compound I:4.

Yoneyama teaches L-158,809 is a new angiotensin II type 1 receptor antagonist (abstract) (according to STN RN 133240-46-7, L 158809 is a common name used for compound I:4; see STN RN listing; CN L 158808 with associated structure); blood pressure reduction is shown for 0.03 mg/kg, 0.3 mg/kg and 3 mg/kg (p. 194, Figure 1). 3 mg/kg administered to a 40 g mouse would correspond to 0.12 mg dosage; 3 mg/kg administered to a 7 kg dog would correspond to a 21 g dosage; 3 mg/kg administered to a 70 kg human would correspond to a 210 mg dosage. It would have been obvious to one of ordinary skill in the art at the time of the invention to administer compound I:4 in place of irbesartan in the treatment of metabolic syndrome taught by Ortlepp, giving the method of the instant claims. It would also have been obvious to optimize the method based on blood pressure normalization for mice, dogs and humans, which would have given dosages within the ranges of the instant claims. The motivation to substitute Compound I:4 for irbesartan would have been the substitution of one art-recognized equivalent compound (Compound I:4) for another (irbesartan) in terms of angiotensin II receptor antagonist activity. The motivation to optimize the dosages would have been the routine optimization of amounts used for reduction of blood pressure and other metabolic syndrome symptoms.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is

(571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614